RESEARCH PROTOCOL SAFETY SURVEY

PRINCIPAL INVESTIGATOR (PI):

PROJECT TITLE:

DATE OF SUBMISSION:

LIST VA AND NON-VA LOCATIONS IN WHICH PI CONDUCTS RESEARCH:

1. DOES THE RESEARCH INVOLVE THE USE OF ANY OF THE FOLLOWING?

a. Biological Hazards (Microbiological or viral agents, pathogens, toxins, select agents as defined in Title 42 Code of Federal Regulations (CFR) 72.6, or animals) YES ☐ NO ☐

b. Human or non-human cell or tissue samples (including cultures, tissues, blood, other bodily fluids or cell lines) YES ☐ NO ☐

(1) Have all research personnel received or been offered hepatitis B vaccine free of charge from Employee Health at the VAMC? YES ☐ NO ☐

(2) Will you be shipping specimens or dangerous goods? YES ☐ NO ☐

(3) If yes, have personnel received training in Shipping of Specimens (TMS Module # NFED 4501918 YES ☐ NO ☐

c. Recombinant deoxyribonucleic acid (DNA) YES ☐ NO ☐

d. Chemicals:

(1) Toxic chemicals (including heavy metals) YES ☐ NO ☐

(2) Flammable, explosive, or corrosive chemicals YES ☐ NO ☐

(3) Carcinogenic, mutagenic, or teratogenic chemicals YES ☐ NO ☐

(4) Toxic compressed gases YES ☐ NO ☐

(5) Acetylcholinesterase inhibitors or neurotoxins YES ☐ NO ☐

e. Controlled Substances YES ☐ NO ☐

f. Ionizing Radiation:

(1) Radioactive materials YES ☐ NO ☐

(2) Radiation generating equipment YES ☐ NO ☐

g. Nonionizing Radiation:

(1) Ultraviolet Light YES ☐ NO ☐

(2) Lasers (class 3b or class 4) YES ☐ NO ☐

If the answer to any of these questions is YES, complete all sections of this survey that apply.

If all answers are NO, a documented review by the local Subcommittee on Research Safety is still required prior to submission. If the research involves the use of human subjects or human tissues, Institutional Review Board (IRB) review is required. ***NOTE:*** *Use of animals also requires submission of an Institutional Animal Care and Use Committee (IACUC)-approved Animal Component.*

(3) Radiofrequency or microwave sources YES ☐ NO ☐

2. BIOLOGICAL HAZARDS

a. Does your research involve the use of microbiological or viral agents, pathogens, toxins, poisons or venom? YES ☐ NO ☐

If **NO**, skip to the section on **Cells and Tissue Samples**.

If **YES**, list all Biosafety Level 2 and 3 agents or toxins used in your laboratory. It is the responsibility of each PI to:

(1) Consult either:

(a) The National Institutes of Health (NIH)-Center for Disease Control and Prevention (CDC) publication entitled Biosafety in Microbiological and Biomedical Laboratories or

(b) The CDC online reference (http://www.cdc.gov)

(2) Identify the Biosafety Level (also called Risk Group) for each organism, agent, or toxin. Enter it into the following table.

Organism, Agent, or Toxin	**Biosafety Level****

** For **each Biosafety Level 2 or 3 agent or toxin** listed, provide the information requested on the following page(s). (Description of Biosafety Levels 2 and 3 can be found in Appendix A.)

b. Are any of the biohazardous agents listed above classified as a "Select Agent" by the Centers for Disease Control? YES ☐ NO ☐

3. BIOLOGICAL HAZARDS – Description of Use ***NOTE:*** *Photocopy this page, as necessary.*

a. Identify the microbiological agent or toxin (name, strain, etc.):

b. If this is a Select Agent (42 CFR 72.6), provide the CDC Laboratory Registration # and the date of the CDC inspection:

c. Indicate the largest volume and/or concentration to be used:

d. Indicate whether antibiotic resistance will be expressed, and the nature of this antibiotic resistance:

e. Describe the containment equipment (protective clothing or equipment, biological safety cabinets, fume hoods, containment centrifuges, etc. including most recent inspections dates) to be used in this research:

f. Describe the proposed methods to be employed in monitoring the health and safety of personnel involved in this research:

4. CELLS and TISSUE SAMPLES

a. Will personnel work with animal blood, human or non-human primate blood, body fluids, organs, tissues, cell lines or cell clones? YES ☐ NO ☐

If yes, specify:

b. Will research studies represent a potential biohazard for lab personnel?

NA ☐ YES ☐ NO ☐

If yes, specify the potential hazard and precautions employed to protect personnel in the laboratory:

NOTE: *If these studies involve animals, the Animal Component of Research Protocol (ACORP) must be completed*.

c. Specify precautions employed to protect personnel working in the laboratory:

5. RECOMBINANT DNA

a. Are procedures involving recombinant DNA used in your laboratory? YES ☐ NO ☐
If **NO**, skip to the section on **Use of Chemicals**.

b. Are recombinant DNA procedures used in your laboratory limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)? YES ☐ NO ☐

(1) If **YES**, your recombinant DNA studies are exempt from restrictions described in the NIH Guidelines for Research Involving Recombinant DNA Molecules.

(2) If **NO**, it is the responsibility of each PI to:

(a) Consult the current NIH Guidelines for Research Involving Recombinant DNA Molecules which can be found at the Internet site http://www4.od.nih.gov/oba/rac/guidelines/guidelines.htm.

(b) Identify the experimental category of their recombinant DNA research.

c. **Description of Recombinant DNA Procedures:**

(1) Identify the NIH classification (and brief description) for these recombinant DNA studies:

(2) Biological source of DNA insert or gene:

(3) Function of the insert or gene:

(4) Vector(s) used or to be used for cloning (e.g., pUC18, pCR3.1):

(5) Host cells and/or virus used or to be used for cloning (e.g., bacterial, yeast or viral strain, cell line):

6. USE OF CHEMICALS

a. Has the use of chemicals in your laboratory been reviewed by an appropriate committee or subcommittee in the past 12 months? YES ☐ NO ☐

b. Are personnel knowledgeable about the special hazards posed by:

(1) Carcinogens?	NA ☐	YES ☐	NO ☐
(2) Teratogens and Mutagens?	NA ☐	YES ☐	NO ☐
(3) Toxic gases?	NA ☐	YES ☐	NO ☐
(4) Neurotoxins?	NA ☐	YES ☐	NO ☐
(5) Reactive and potentially explosive compounds?	NA ☐	YES ☐	NO ☐

NOTE: *Submission of the laboratory chemical inventory is required for local review.*

7. CONTROLLED SUBSTANCES

a. Does your research involve the use of any substance regulated by the Drug Enforcement Agency? YES ☐ NO ☐

If yes, list the controlled substances to be used:

b. Are all Schedule II and III drugs stored in a double-locked vault

NA ☐ YES ☐ NO ☐

NOTE: *The schedule of controlled substances can be found at the Internet site*
http://www.usdoj.gov/dea/pubs/schedule.pdf
https://www.dea.gov/drug-information/drug-scheduling

8. RADIOACTIVE MATERIALS

The purchase, handling, receipt and disposal of radionuclides must be performed as specified by the investigator's license. The site where the work is being performed determines which license the investigator must use. Work performed at ETSU must be done under the authority of the ETSU (State of Tennessee) license. Work being performed at the VA must be done under the authority of the VA license.

Investigators working at ETSU with a State of TN license using VA funding to purchase radionuclides, must follow State of TN guidelines for radioactive materials. Purchasing will be done by ETSU to ensure delivery to ETSU (and not the VA warehouse). Appropriate arrangements must be made with the VA Research Office (Ext 2859) for a contract to reimburse ETSU for purchasing and disposal costs.

In all cases, projects utilizing radioactive materials must have budget line item for disposal costs.

Does your research involve the use of radioactive materials? YES ☐ NO ☐

If YES, provide the following:

a. Identity of radioactive source (s):

b. Radiation Safety Committee Approval (date):

9. PHYSICAL HAZARDS

a. Are physical hazards addressed in the facility Occupational Safety and Health Plan?
YES ☐ NO ☐

b. Do employees receive annual training addressing physical hazards?
YES ☐ NO ☐

Acknowledgement of Responsibility and Knowledge

I certify that my research studies will be conducted in compliance with and full knowledge of Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of, biohazardous materials, chemicals, radioisotopes, and physical hazards. I further certify that all technical and incidental workers involved with my research studies will be aware of potential hazards, the degree of personal risk (if any), and will receive instructions and training on the proper handling and use of biohazardous materials, chemicals, radioisotopes, and physical hazards. A chemical inventory of all Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA)-regulated hazardous chemicals is attached to this survey.

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Principal Investigator's Signature **Date**

Certification of Safety Officer's Approval

A complete list of chemicals to be used in the proposal has been reviewed. Appropriate occupational safety and health, environmental, and emergency response programs will be implemented based on the list provided.

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Safety Officer's Signature **Date**

Certification of Research Approval

The safety information for this application has been reviewed and is in compliance with Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of biohazardous materials, chemicals, radioisotopes, and physical hazards. Copies of any additional surveys used locally are available from the Research and Development (R&D) Office.

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Chair, Subcommittee on Research Safety **Date**

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Chair, Research & Development Committee **Date**

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Radiation Safety Officer (if applicable) **Date**

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Facility Safety Officer **Date**